

- C L A I M S

1. A process for producing an iron-dextran compound, in which the molecular weight of a dextran is
5 reduced by hydrolysis, and functional aldehyde terminal
groups thereof converted into alcohol groups by hydrogenation; said dextran as an aqueous solution is
combined with at least one water-soluble ferric salt;
base is added to the resulting solution to form ferric
10 hydroxide, and the resulting mixture is heated to
transform the ferric hydroxide into ferric oxyhydroxide
as an association compound with the dextran,
characterized in that the hydrogenation is
only partial, leaving, however, at the most 15% by
15 weight reducing sugar, calculated on the total amount
of carbon hydrates, and said dextran before being
combined with the ferric salt, and after being sub-
jected to hydrogenation is subjected to an oxidation,
said hydrogenation and oxidation being performed to
20 obtain dextran having substantially all aldehyde groups
converted into alcohol and carboxylic groups.

2. A process according to claim 1, characterized
in that the dextran before being combined
with the at least one ferric salt has a weight
25 mean molecular weight less than 7,000 Da.

3. A process according to claim 1 or 2,
characterized in that after the hydroly-
sis, but before being combined with the water-soluble
ferric salt, the dextran is purified by one or more
30 membrane separations having a cut-off value suitable
for holding back dextran molecules above 2,700 Da,
possibly followed by further hydrolysis and one or more
membrane separations having a cut-off value between 340
and 800 Da removing the smaller molecules.

4. A process according to any of claims 1-3 characterized in that the dextran molecules have a reducing sugar content not above 4% b.w. after the oxidation.

5 5. A process according to any of claims 1-4, characterized in that the hydrogenation is performed by means of sodium borohydride in aqueous solution.

6. A process according to any of claims 1-5, characterized in that the oxidation is performed by means of a hypochlorite, preferably sodium hypochlorite in basic aqueous solution.

7. A process according to any of the preceding claims, characterized in the following 15 steps:

preparing an aqueous solution comprising the hydrogenated and oxidized dextran and at least one water-soluble ferric salt;

adjusting the pH of said aqueous solution to a value above 10 by addition of a base;

heating the mixture to a temperature above 100°C until it turns into a black or dark brown colloidal solution and is filterable through a 0.45 µm filter;

purification and stabilization of the solution using filtration, heating and membrane separations and addition of one or more stabilizers, and

optionally drying the solution to obtain the desired iron-dextran compound as a stable powder.

8. A process according to claim 7, characterized in that the stabilisation comprises addition of at least one salt of an organic hydroxy acid, preferably selected from citrates and gluconates.

9. A process for producing a dextran preparation, in which process the molecular weight of a dextran is reduced by hydrolysis, and functional aldehyde terminal

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groups thereof converted into alcohol groups by hydrogenation; characterized in that the hydrogenation is only partial, leaving, however, at the most 15% by weight reducing sugar, calculated on the total amount of carbon hydrates, and said dextran is subsequently subjected to oxidation, said hydrogenation and oxidation being performed to obtain dextran having substantially all aldehyde groups converted into alcohol and carboxylic groups.

10 10. Iron-dextran compound produced according to claims (1-8), characterized in that its apparent peak molecular weight (Mp) is 50.000-150.000 Da, preferable 70.000-130.000, more preferable 80.000-120.000 Da and its iron content is 15-45 % b.w..

11 11. Dextran preparation obtainable by a process according to claim 9.

12. Dextran preparation according to claim 11, obtained by a process according to claim 9.

13. A pharmaceutical composition for prophylaxis or treatment of iron-deficiency by parenteral administration comprising a compound according to claim 10.

14. A pharmaceutical composition according to claim 13, characterized in that it comprises a salt of an organic hydroxy acid, preferably selected from citrates and gluconates as stabilizer.

15. Use of an iron-dextran compound according to claim 10, for preparation of a parenterally administrable therapeutical composition for prophylaxis or treatment of iron-deficiency by parenteral administration.

16. Use of an dextran preparation obtainable by a process according to claim 9, for the production of an iron-dextran compound.

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